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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,515	10/03/2001	Christophe Bonny	20349-501DIV	2764

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EXAMINER
STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
1652	6

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/970,515	BONNY, CHRISTOPHE	
	Examiner	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,20 and 23-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,20 and 23-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

[1] Claims 1, 20, and 23-32 are pending in the application.

[2] Applicant's cancellation of claims 2-19, 21, and 22, amendment to claims 1, 23, and 24, and addition of claims 25-32 in Paper No. 5, filed May 27, 2003, is acknowledged.

[3] Applicant's election without traverse of Group II, original claims 1-13 and 15-24, drawn to a peptide comprising the generic peptide of SEQ ID NO:6 including the species of SEQ ID NO:4 is acknowledged.

Priority

[4] Applicant claims domestic priority under 35 USC 119(e) to provisional Application No. 60/158,774, filed October 12, 1999 and claims domestic priority under 35 USC 121 to non-provisional Application No. 09/503,954, filed February 14, 2000. It is noted that the sequences of SEQ ID NO:4 (in the L-configuration) and SEQ ID NO:8 are disclosed in Figure 1 of provisional Application No. 60/158,774.

Sequence Compliance

[5] This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the specification. It is particularly noted that the specification discloses nucleotide and amino acid sequences that have not been identified by sequence identification numbers (page 36, lines 12 and 13 and the descriptions of Figures 1 and 2 at page 3, lines 6-8 of the specification). See particularly 37 CFR 1.821(d). It is noted that if these sequences are not present in the sequence listing, applicant must provide a computer readable form (CRF) copy of the

"Sequence Listing" containing these sequences, an initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d).

[6] It is noted that the sequences of SEQ ID NO: 3, 4, 6, 8, 10, and 14-16 have not been disclosed in the computer readable form of the sequence listing or the paper copy thereof. The specification discloses that these peptides are D retro-inverso peptides (see pages 5, 7, and 15 of the specification). 37 CFR 1.821(a)(2) states, "[t]hose amino acid sequences containing D-amino acids are not intended to be embraced by this definition" referring to the definition of "amino acid" in amino acid sequences that must satisfy the sequence rules. Therefore, the amino acid sequences of SEQ ID NO: 3, 4, 6, 8, 10, and 14-16 are amino acid sequences that are not encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821(a)(2) and the sequences of these peptides are not required in the sequence listing.

Specification/Informalities

[7] It is noted that the "Request for Continuation Application Pursuant to 37 C.F.R. 1.53(b)" of Paper No. 1 indicates that there are 37 pages of specification and 3 pages of claims. However, the instant application has only 36 pages of specification (pages 1-36 of the specification) and 4 pages of claims (pages 37-40 of the specification).

[8] The use of the trademark "Gene Gun®" has been noted in this application (page 25, line 13 of the specification). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

[9] The specification is objected to for the use of the character "□" (see page 35, line 20; page 36, lines 14, 15, and 18 of the specification). Applicant should replace "□" with the appropriate symbol or character.

[10] It is noted that applicant incorrectly discloses the filing date of application number 09/503,954 at page 1, line 4 of the specification. Instead of February 14, 2001, the correct filing date is February 14, 2000. Appropriate correction is required.

[11] Regarding applicant's claim for domestic priority under 35 USC § 121 to application number 09/503,954, it is noted that the first paragraph of the specification provides no disclosure of the relationship of the instant application to earlier filed application number 09/503,954. MPEP § 201.11(III) states, "Except for benefit claims to the prior application in a continued prosecution application (CPA), benefit claims under 35 U.S.C. 120, 121, and 365(c) must identify the prior application by application number, or by international application number and international filing date, *and indicate the relationship between the applications*" (italics added for emphasis). A statement listing the relationship of the instant application to earlier filed application number 09/503,954 and a statement regarding the current status of application number 09/503,954 is required. The following example is provided: "This application is a divisional application of Application No. 09/503,954, filed February 14, 2000, now pending, which claims benefit of provisional Application No. 60/158,774, filed October 12, 1999."

Claim Objection(s)

[12] Claims 23, 26, 28, and 29 are objected to because of the following informalities: the term "amino acid sequence" is grammatically incorrect and should be replaced with, for example, "amino acid sequences". Appropriate correction is required.

Claim Rejection(s) - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[13] Claims 23, 26, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23 (claim 31 dependent therefrom) is drawn to a genus of chimeric peptides *comprising* SEQ ID NO:4 and SEQ ID NO:8, wherein said peptide inhibits JNK phosphorylation of c-Jun, ATF2, and Elk1. Claim 26 (claim 30 dependent therefrom) is drawn to a genus of chimeric peptides *comprising* SEQ ID NO:4 and SEQ ID NO:10, wherein said peptide inhibits JNK phosphorylation of c-Jun, ATF2, and Elk1. It is noted that the claims use the transitional phrase "comprising", which is "inclusive or open-ended" according to MPEP § 2111.03. It is further noted that the specification indicates the term "peptide" implies "no particular length" (page 6, lines 5 and 6 of the specification). Thus, the claimed peptides are not limited to a particular length and can have any number of additional amino acids added to the recited amino acid sequences. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species that are adequately described are representative of the entire genus. The claimed genus of peptides encompasses proteins having any number of additional amino acids to the peptides of SEQ ID NO:4 and 8 or 10, including fusion proteins, that have not been disclosed in the specification. Such fusion proteins have the potentiality of having functions other than the ability to inhibit JNK phosphorylation of c-Jun, ATF2, and Elk1. Beyond the characterization of a chimeric peptide of SEQ ID NO:4 and 8 or 10,

the specification provides no disclosure of the structures of peptides *comprising* SEQ ID NO:4 and 8 or 10, which would indicate that applicant had possession of the claimed genus of chimeric peptides. Thus, the genus encompasses species that are *widely variant* in structure and function. As such, neither the description of the structure of SEQ ID NO:4 and 8 or 10, nor the disclosure of a structural feature present in all members of the claimed genus, i.e., SEQ ID NO:4 and 8 or 10, is sufficient to be representative of the attributes and features of the entire genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

[14] Claims 23, 26, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a chimeric peptide of SEQ ID NO:4 and 8 or a chimeric peptide of SEQ ID NO:4 and 10, wherein the chimeric peptide inhibits JNK phosphorylation of c-Jun, ATF2, and Elk1, does not reasonably provide enablement for *all* chimeric peptides *comprising* SEQ ID NO:4 and 8 or 10 that inhibit JNK phosphorylation of c-Jun, ATF2, and Elk1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Undue experimentation would be required for a skilled artisan to make and/or use the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s). The Factors most relevant to the instant rejection are addressed below.

- The claims are overly broad in scope: Claim 23 (claim 31 dependent therefrom) is so broad as to encompass *all* chimeric peptides *comprising* SEQ ID NO:4 and SEQ ID NO:8, wherein said peptide inhibits JNK phosphorylation of c-Jun, ATF2, and Elk1. Claim 26 (claim 30 dependent therefrom) is so broad as to encompass *all* chimeric peptides *comprising* SEQ ID NO:4 and SEQ ID NO:10, wherein said peptide

inhibits JNK phosphorylation of c-Jun, ATF2, and Elk1. As stated above, the claims use the transitional phrase "comprising", which is "inclusive or open-ended" according to MPEP § 2111.03. Also, the specification indicates the term "peptide" implies "no particular length" (page 6, lines 5 and 6 of the specification). Thus, the claimed peptides are not limited to a particular length and can have any number of additional amino acids added to the recited amino acid sequences. The scope of the claims is *not* commensurate with the enablement provided by the disclosure with regard to the extremely large number of peptides *comprising* SEQ ID NO:4 and 8 or 10 of any length with the ability to inhibit JNK phosphorylation of c-Jun, ATF2, and Elk1 broadly encompassed by the claims. In this case, the disclosure is limited to a chimeric peptide of SEQ ID NO:4 and 8 or 10, wherein the chimeric peptide inhibits JNK phosphorylation of c-Jun, ATF2, and Elk1.

- The lack of guidance and working examples: The specification provides only two working examples of the broad scope of chimeric peptides encompassed by the claims, i.e., a chimeric peptide of SEQ ID NO:4 and SEQ ID NO:8(SEQ ID NO:15) or a chimeric peptide of SEQ ID NO:4 and SEQ ID NO:10. However, these working examples fail to provide the necessary guidance for making the entire scope of claimed chimeric peptides, which encompass proteins having *any number* of additional amino acids added to the amino acid sequences of SEQ ID NO:4 and 8 or 10 with an expectation of generating a chimeric peptide that maintains the ability to inhibit JNK phosphorylation of c-Jun, ATF2, and Elk1. Predictability of which additional amino acids can be added to the amino acid sequence of a peptide inhibitor and obtain a protein or peptide with the desired activity requires a knowledge of and guidance with regard to the effects of additional amino acids on the folding of the peptide inhibitor and the resulting effects on the region(s) of interaction between the peptide and the target of inhibition. In this case, such guidance has not been provided.
- The high degree of unpredictability of the art: The amino acid sequence of a peptide inhibitor determines its ability to actively inhibit a given protein. One of skill in the art recognizes the high degree of unpredictability that the relatively small peptide sequence of SEQ ID NO:4 (21 amino acids) will maintain its ability to inhibit JNK phosphorylation when additional amino acids are added to its

sequences. The effects of additional amino acids on the folding of the peptide and the resulting effects on the interaction of the peptide with JNK, i.e., whether the chimeric peptide maintains the ability to inhibit JNK phosphorylation of c-Jun, ATF2, and Elk1, are *highly* unpredictable. The state of the prior art supports this high degree of unpredictability as described above, e.g., Branden et al. ("Introduction to Protein Structure", Garland Publishing Inc., New York, 1991) teach that protein engineering experiments reveal how little is known about the rules of protein stability and the energetics of ligand binding and emphasize how difficult it is to design *de novo* stable proteins with specific functions (page 247). Thus, a skilled artisan would recognize the high degree of unpredictability that *all* chimeric peptides *comprising* SEQ ID NO:4 and 8 or 10 and having any number of additional amino acids would retain the ability to inhibit JNK phosphorylation of c-Jun, ATF2, and Elk1.

- The amount of experimentation required is undue: While recombinant screening techniques are known, it is *not* routine in the art to screen *all* chimeric peptides having *any number* of additional amino acids added to the amino acid sequences of SEQ ID NO:4 and 8 or 10 for the ability to inhibit JNK phosphorylation of c-Jun, ATF2, and Elk1. In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability in the art as evidenced by Branden et al., undue experimentation would be necessary for a skilled artisan to make and use the entire scope of claimed polypeptides.

Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re* Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re* Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejection(s) - Double Patenting

[15] The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

[16] Claims 1, 20, 25, 26, and 28-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 26, 44, 46, 50, 52, 53, and 58 of copending Application No. 09/503,954 (hereafter referred to as "Application '954"). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed Cir 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1, 26, 44, 46, 50, 52, 53, and 58 of Application '954 are drawn to peptides comprising or consisting of SEQ ID NO:6, SEQ ID NO:6 and SEQ ID NO:10, or a peptide consisting of SEQ ID NO:6 and SEQ ID NO:8 and compositions thereof. The peptides and compositions of claims 1, 26, 44, 46, 50, 52, 53, and 58 of Application '954 differ from the

peptides and compositions of claims 1, 20, 25, 26, and 28-30 of the instant application in that the peptides and compositions of claims 1, 26, 44, 46, 50, 52, 53, and 58 of Application '954 recite SEQ ID NO:6 instead of SEQ ID NO:4. The specification of Application '954 discloses SEQ ID NO:4 as a species of the generic peptide of SEQ ID NO:6. Application '954 discloses the JNK inhibitor peptide of the invention can be the generic retro-inverso peptide having the sequence of SEQ ID NO:6 (page 7). The peptide of SEQ ID NO:6 is generic to the peptide species of SEQ ID NO:4 (pages 6 and 7) and Application '954 discloses that one embodiment of the invention is the D retro-inverso peptide of SEQ ID NO:4 (page 7). Claims 1, 20, 25, 26, and 28-30 of the instant application cannot be considered patentably distinct over claims 1, 26, 44, 46, 50, 52, 53, and 58 of Application '954 when there is a specifically recited embodiment in Application '954 that supports claims 1, 26, 44, 46, 50, 52, 53, and 58 of that application and falls within the scope of claims 1, 20, 25, 26, and 28-30 of the instant application because it would have been obvious to one having ordinary skill in the art for the peptides and compositions of claims 1, 26, 44, 46, 50, 52, 53, and 58 of Application '954 to have the sequence of SEQ ID NO:4 as SEQ ID NO:4 is a specifically defined species of the generic sequence of claimed SEQ ID NO:6. One of ordinary skill in the art would have been motivated for the peptides and compositions of claims 1, 26, 44, 46, 50, 52, 53, and 58 of Application '954 to have the sequence of SEQ ID NO:4 as a species of the generic sequence of SEQ ID NO:6 because the sequence of SEQ ID NO:4 is disclosed as being an embodiment of the generic sequence of SEQ ID NO:6.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

[17] Claims 23 and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 44 and 58 of copending Application No. 09/503,954 (Application '954). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed Cir 1998); *In re Goodman*,

11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 44 and 58 of Application '954 are drawn to peptides comprising SEQ ID NO:6 and SEQ ID NO:10 and a composition thereof. The peptide and composition of claims 44 and 58 of Application '954 differ from claims 23 and 31 of the instant application in that claims 44 and 58 of Application '954 recite SEQ ID NO:6 instead of SEQ ID NO:4 and recite SEQ ID NO:10 instead of SEQ ID NO:8. The specification of Application '954 discloses SEQ ID NO:4 as a species of the generic peptide of SEQ ID NO:6 and SEQ ID NO:8 as a species of the generic peptide of SEQ ID NO:10. As stated above, Application '954 discloses the JNK inhibitor peptide of the invention can be the generic retro-inverso peptide having the sequence of SEQ ID NO:6 (page 7). The peptide of SEQ ID NO:6 is generic to the peptide species of SEQ ID NO:4 (pages 6 and 7) and Application '954 discloses that one embodiment of the invention is the D retro-inverso peptide of SEQ ID NO:4 (page 7). Application '954 further discloses the TAT trafficking sequence of the invention can be a generic D retro-inverso peptide having the sequence of SEQ ID NO:10 (page 15), which is generic to the peptide species of SEQ ID NO:8 (page 6, Table 1 and pages 33, bottom and 34, top). Claims 23 and 31 of the instant application cannot be considered patentably distinct over claims 44 and 58 of Application '954 when there is a specifically recited embodiment in Application '954 that supports claims 44 and 58 of that application and falls within the scope of claims 23 and 31 of the instant application because it would have been obvious to one having ordinary skill in the art for the peptide and composition of claims 44 and 58 of Application '954 to have the sequence of SEQ ID NO:4 as a species of the generic sequence of claimed SEQ ID NO:6 and SEQ ID NO:8 as a species of the generic sequence of claimed SEQ ID NO:10 because SEQ ID NO:4 is a specifically defined species of the generic sequence of SEQ ID NO:6 and SEQ ID NO:8 is a specifically defined species of SEQ ID NO:10. One of ordinary skill in the art would have been motivated for the peptide and composition of claims 44 and 58 of Application '954 to have the sequence of SEQ ID NO:4 as a species of the generic sequence of SEQ ID NO:6 and SEQ ID NO:8 as a species of the generic sequence of SEQ ID NO:10 because the sequence of SEQ ID NO:4 is

disclosed as being an embodiment of the generic sequence of SEQ ID NO:6 and the sequence of SEQ ID NO:8 is disclosed as being an embodiment of the generic sequence of SEQ ID NO:10.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

[18] Claims 24, 27, 30, and 32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 44 and 58 of copending Application No. 09/503,954 (Application '954). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed Cir 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 44 and 58 of Application '954 are drawn to peptides comprising SEQ ID NO:6 and SEQ ID NO:10 and a composition thereof. The peptide and composition of claims 44 and 58 of Application '954 differ from claims 24, 27, 30, and 32 of the instant application in that claims 44 and 58 of Application '954 recite a fusion peptide comprising the generic sequences of SEQ ID NO:6 and 10, while the claims of the instant application recite a fusion peptide comprising or consisting of SEQ ID NO:15. The specification of Application '954 discloses SEQ ID NO:15 as a species of a fusion peptide comprising SEQ ID NO:6 and SEQ ID NO:10 by disclosing that an embodiment of the invention is the D retro-inverso peptide of SEQ ID NO:15 (page 6, Table 1 and page 15, lines 9 and 10). Claims 24, 27, 30, and 32 of the instant application cannot be considered patentably distinct over claims 44 and 58 of Application '954 when there is a specifically recited embodiment in Application '954 that supports claims 44 and 58 of that application and falls within the scope of claims 24, 27, 30, and 32 of the instant application because it would have been obvious to one having ordinary skill in the art for the peptide and composition of claims 44 and 58 of Application '954 to have the sequence of SEQ ID NO:15. One of ordinary skill in the art would have been motivated for the peptide and composition of claims 44 and 58

of Application '954 to have the sequence of SEQ ID NO:15 because the peptide of SEQ ID NO:15 is disclosed as being an embodiment of a fusion peptide of the claimed sequences of SEQ ID NO:6 and SEQ ID NO:10.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

[19] It is noted that, at the time of drafting the instant Office action, the following co-pending applications having a common inventor with the instant application were not available to the examiner: Application No. 10/110,430 and Application No. 10/342,683. Once these applications become available to the examiner, the claims of these applications will be evaluated for double patenting with the claims of the instant application.

Reference of Interest

[20] The following reference published after the earliest effective filing date of the instant application has been cited as being relevant to the claimed subject matter:

- Bonny et al. "Cell Permeable Peptide Inhibitors of JNK" *Diabetes* (2001) 50:77-82.

Conclusion

[21] Status of claims:

- Claims 1, 20, and 23-32 are pending.
- Claims 1, 20, and 23-32 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for official papers filed to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

07/22/03